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Guidelines for the Safe Use of Diagnostic Ultrasound

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Guidelines for the Safe Use of Diagnostic Ultrasound

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Table of Contents

1.	**Scope and Purpose**	**5**
2.	**Recommendations**	**7**
2.1	General	7
2.2	Thermal Effects	7
2.3	Mechanical Effects	8
2.4	Device Performance	9
2.5	Quality Assurance	10
3.	**Conclusions**	**11**
3.1	General	11
3.2	Thermal Effects	11
3.3	Mechanical Effects	13
4.	**Rationale**	**15**
4.1	Thermal Effects	15
4.1.1	Exposure Parameters	15
4.1.2	Biological Effects	16
4.1.3	Human Exposure and Clinical Significance	17
4.2	Mechanical Effects	20
4.2.1	Exposure Parameters	20
4.2.2	Biological Effects	21
4.2.3	Human Exposure and Clinical Significance	23
5.	**References**	**26**
6.	**Glossary of Terms**	**31**

1. Scope and Purpose

Diagnostic ultrasound is a valuable modality and is not contraindicated where medical benefit is expected. Furthermore, there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments. However, the possibility exists that such biological effects may be identified in the future. Therefore, the intent of these guidelines is to help equipment manufacturers and operators ensure both the prudent use of diagnostic ultrasound and the continued excellence of its safety record. To this end, the guidance in this document should help equipment operators to identify exposures that are potentially hazardous and to ensure that the exposures they use are justified.

Manufacturers are also reminded to ensure that Health Canada has licensed any of their diagnostic ultrasound devices that are offered for sale or lease in Canada. Licensing requirements can be obtained from the Licensing Division of Health Canada's Medical Devices Bureau.

This update replaces all parts of Safety Code 23 "Guidelines for the Safe Use of Ultrasound – Part 1: Medical and Paramedical Applications (1989)" pertaining to the safe use of diagnostic ultrasound devices. Several developments in the past decade have necessitated this update. First, methods have been developed for estimating the maximum temperature elevation in exposed tissues during clinical examinations (see Sections 3.2 and 4.1). These estimates indicated that during some Doppler blood flow examinations, temperature elevations could exceed 1 °C. Computed estimates of maximum temperature elevations have been as high as 6-10 °C. Also, biological effects studies have demonstrated capillary hemorrhaging *in vivo* in the lungs of several mammalian species (though not humans), as a result of pulsed ultrasound exposures in the range of those available from diagnostic devices, including B-mode imaging. This effect was purely mechanical, having been found in the absence of ultrasonic heating (see Sections 3.3 and 4.2).

In addition to these discoveries, regulatory changes in the U.S.A. have increased the potential for relatively high acoustic outputs to be available (U.S Food and Drug Administration 1997). Also, a voluntary standard was developed for diagnostic ultrasound devices to provide the equipment operator with a real-time display of **Thermal** and **Mechanical Indices**. These exposure indices are related to the potential for heating or mechanical effects, respectively, during the ultrasound examination (AIUM/NEMA 1998a, Abbott 1999).

The information presented in this update summarizes these developments and forms the basis for new recommendations for users and manufacturers. The update is also heavily based on U.S. and other national and international recommendations and guidelines for the safe use of diagnostic ultrasound (Barnett, *et al.*, 2000, AIUM 2000).

The required new terminology is in bold in the text and is explained in the Glossary of Terms, Section 6. In this glossary, the terms used in the guidelines are explained primarily for equipment operators and other interested parties. This is done in as plain language as possible without distorting the meaning of the term. Of particular note is the extension of the **ALARA** principle to ultrasound exposures.

Manufacturers endeavouring to implement this document's recommendations for device performance will need to consult the referenced standards and the U.S. Food and Drug Administration 510(k) guidance document (1997).

2. Recommendations

2.1 General

(1) The use of diagnostic ultrasound to obtain information about function or structure in human beings should be restricted to situations in which the medical benefit that may accrue from the diagnostic data outweighs any foreseeable risk. Most such situations are limited to clinical examinations of the ill or potentially ill patient, or pregnant women. Where available, Canadian clinical practice and operator training guidelines should be used to help maximize the benefit of an examination.

(2) Situations of training, demonstration or research may also provide a medical benefit from diagnostic data that outweighs any foreseeable risk. Here, information is obtained for people who are not necessarily in the categories of Recommendation (1), above. In all situations of training, demonstration or research, if either of the **Thermal Index** or **Mechanical Index** will be greater than 1, then a subject should be informed of the anticipated exposure condition and how it compares in safety with conditions for normal diagnostic practice.

(3) Ultrasound should not be used for any of the following:

(i) to have a picture of the fetus, solely for *non-medical* reasons;

(ii) to learn the sex of the fetus solely for *non-medical* reasons; and

(iii) for commercial purposes, such as trade shows, or producing pictures or videos of the fetus.

2.2 Thermal Effects

(1) M-mode, pulsed Doppler and Colour Flow Imaging are valuable clinical tools and, despite potential risks, are not contraindicated. However operators should be careful to limit exposure to critical structures and utilize the exposure information provided by the manufacturer.

(2) In particular, users should employ exposures which are **As Low As Reasonably Achievable(ALARA)**[1] because of the potential for **ultrasonic heating** of tissue during M-mode imaging and, normally to a significantly greater extent, Doppler ultrasound blood flow examinations. For devices which comply with the AIUM/NEMA *Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 1, 1998* (Output Display Standard), implementation of the **ALARA** principle can be achieved by using the real-time display of the relevant **Thermal Index** to assess the potential for **ultrasonic heating.** Guidance on potentially hazardous exposures is found in Section 3.2.

(3) Exposure can be reduced by either reducing the **Thermal Index** using output controls or by reducing the **dwell time**, the amount of time that the transducer remains in one place (AIUM 1994).

2.3 Mechanical Effects

(1) Users should employ exposures, in any relevant mode, which are **As Low As Reasonably Achievable (ALARA)** because of the potential for:

(i) ultrasonically induced capillary hemorrhaging in lung if it is exposed during pediatric diagnostic ultrasound examinations, particularly for infants and neonates, especially if they are pre-term;

(ii) ultrasonically induced capillary hemorrhaging of the intestine where intestinal peristalsis is inhibited or conditions promote intraluminal or submucosal gas collections;

(iii) ultrasonically induced capillary hemorrhaging in other soft tissues when Gas Contrast Agents are used.

(2) Use of Gas Contrast Agents in a diagnostic ultrasound examination is not recommended within 24 hours before extracorporeal shock wave lithotripsy.

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1. Section 6 (Glossary) provides more information about the extension of the ALARA principle to diagnostic ultrasound.

(3) Implementation of the **ALARA** principle can be achieved by using the real-time display of the **Mechanical Index**,to assess the potential for capillary hemorrhaging. If the **Mechanical Index (MI)** can exceed 1, then, for devices to comply with the Output Display Standard, the **MI** must be given in B-mode.

(4) Exposure can be reduced by lowering the **Mechanical Index** using output controls. Reducing the **dwell time** is of use if threshold pressures are exceeded.

Guidance on the likelihood and clinical significance of injury due to mechanical effects is given in Section 3.3.

2.4 Device Performance

(1) It is recommended that diagnostic ultrasound devices comply with the Output Display Standard (AIUM/NEMA 1998a).

(2) It is recommended that the maximum attainable values for the **Mechanical Index** and the **derated spatial peak time average intensity, I_{spta_3}**, not exceed 1.9 and 720 mW/cm^2, respectively.

(3) For ophthalmic devices or for ophthalmic applications of general purpose devices, the maximum attainable value for the **Thermal Index** should be less than or equal to 1, the maximum attainable value of the **Mechanical Index** should be less than or equal to 0.23 and the maximum attainable value of the **derated spatial peak time average intensity, I_{spta_3}** should be less than or equal to 50 mW/cm^2. With these limits, the Output Display Standard does not require a real-time output display.

(4) For Fetal Heart Rate Monitors, the maximum attainable value of **spatial average, temporal average intensity** at the transducer face should be less than 20 mW/cm^2 for continuous wave devices and the maximum attainable value of the **spatial average, pulse average intensity** at the transducer face should be less than 20 mW/cm^2 for pulsed devices (FDA 1997). These recommended limits were chosen to be consistent with the output level limits in the **U.S. FDA 510(k) guidance document** (FDA 1997). With

these limits for Fetal Heart Rate Monitors, it is unlikely that a **Thermal Index** display would be required under the Output Display Standard.

2.5 Quality Assurance

It is recommended that equipment operators implement quality assurance measures to maintain the capability of obtaining reliable diagnostic information at acoustic exposures which are **As Low As Reasonably Achievable**. Guidance on quality assurance methods can be found in several documents, including Guidelines of the Canadian Society of Diagnostic Medical (CSDMS 1998), as well as publications of the American Institute for Ultrasound in Medicine (AIUM 1991, AIUM 1995a, AIUM 1995b).

As the quality of diagnostic information depends, in part, on operator training, it is also recommended that sonographers (ultrasound technologists) be appropriately qualified and registered with either the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP) or the American Registry of Diagnostic Medical Sonographers (ARDMS).

3. Conclusions

3.1 General

- Although there are many exposure conditions for which the risk of injury during a diagnostic ultrasound examination is negligible, this is not the case for every possible exposure condition using currently available equipment. Therefore, the persons responsible for the ultrasonic exposure must ensure that the exposure is justified, i.e., that reliable diagnostic information can be achieved and that the benefits outweigh the risk.
- The conclusions listed below provide guidance as to the risks due to thermal and mechanical effects arising from ultrasound exposure. To be useful, all the conclusions need to be taken into consideration. Guidance as to the benefit of a diagnostic ultrasound examination can be obtained from clinical practice guidelines available from medical societies and associations in Canada.

3.2 Thermal Effects

- At the time of writing, the information published on output levels during B-mode imaging indicates that the risk of injury from **ultrasonic heating** is negligible during this type of examination. At this time, there appears to be no reason on thermal grounds to limit such scanning for any clinical indication, including ultrasound examination of normal pregnant women.
- In all other operating modes, especially those used for Doppler blood flow examinations, risk of injury from **ultrasonic heating** depends on the temperature elevation and the **dwell time**, as indicated by the conclusions given below.

- If the **Thermal Index (TI)** does not exceed 1, currently available evidence indicates that the risk of an injury due to **ultrasonic heating** is negligible for the vast majority of conditions of the diagnostic ultrasound examination.

- For first trimester transabdominal fetal examinations through a bladder path greater than 5 cm in length, evidence indicates that it is possible that the maximum temperature elevation which could be obtained is as much as 2-3 times that of the displayed **Soft Tissue Thermal Index (TIS)**. More caution may be warranted in these situations, particularly if the **TIS** exceeds 1.

- The **Soft Tissue Thermal Index (TIS)** is the appropriate indicator of the potential for **ultrasonic heating** for examinations in which the ultrasound beam travels a path which is made up principally of homogeneous soft tissue or a soft tissue/fluid path, as in a first trimester fetal examination or an abdominal examination.

- If bone, including 2nd or 3rd trimester fetal bone is within the ultrasound beam, then the **Bone Thermal Index (TIB)** is often the appropriate indicator, except as noted in the next conclusion.

- If bone is in contact with the transducer then the **Cranial Thermal Index (TIC)** is the appropriate indicator. If bone is within about 1 cm of the transducer and this is closer than the nearest focal zone, the **Cranial Thermal Index (TIC)** is the appropriate indicator. More caution may be warranted in these cases because of the potential for transducer self-heating; heating of the transducer may add significantly to any **ultrasonic heating** which may occur.

- Generally, more caution may be warranted for transvaginal, transesophegeal and transrectal examinations because heating of the transducer has the potential to produce additional heat to adjacent tissue.

- This conclusion and the following one provide guidance to the user if the temperature elevation in the fetus could exceed 1 °C as a result of a diagnostic ultrasound exposure. If the exposure produces a maximum *in situ* temperature of no more

than 38.5 °C (1.5 °C above normal physiological levels) then it may be used clinically without reservation on thermal grounds.

- To be considered potentially hazardous on thermal grounds, it appears that a diagnostic ultrasound exposure must elevate embryonic and fetal *in situ* temperatures to the following temperatures for approximately the corresponding durations (see Section 4.1.2):

  39 °C (2 degrees above normal), 60 minutes;
  40 °C,(3 degrees above normal), 15 minutes;
  41 °C,(4 degrees above normal), 4 minutes;
  42 °C,(5 degrees above normal), 1 minute;
  43 °C (6 degrees above normal), 0.25 minutes.

3.3 Mechanical Effects

- At exposures that do not exceed the output limits recommended in Section 2.4, there is no demonstrated risk of clinically significant damage in humans from mechanical effects of ultrasound exposure during a diagnostic examination. However, capillary hemorrhaging has been observed in lung and the intestine of mammals at diagnostically relevant exposures. This effect has also been observed in other soft tissues if gas contrast agents are used. For the most part, thresholds are just as likely to be exceeded for B-mode as for pulsed Doppler or colour flow Doppler modes. However, thresholds are lower for pulsed Doppler modes with relatively long pulses.

- If the **Mechanical Index (MI)** exceeds 1, there is a small risk of capillary hemorrhaging in the lung during ultrasound examinations involving exposure of the neonatal and infant chest. The risk may increase in more unusual exposures where the surface of the lung is near the focus. Although clinically significant hemorrhaging is unlikely, in part because of the small volume of tissue that is affected, the potential for achieving clinical significance may increase in the premature infant.

- At the current maximum values for the **MI** of 1.9, it is unlikely that diagnostic ultrasound exposure would lead to clinically significant intestinal hemorrhage in humans. However, the likelihood may increase for pathologic conditions inhibiting intestinal peristalsis and promoting intra-luminal and submucosal gas collections.
- A limited number of experimental studies suggests that use of ultrasound gas contrast agents (GCAs) (microbubbles) during a diagnostic examination has the potential to increase the likelihood of capillary hemorrhaging in tissues other than lung. In experiments on animals, the risk of significant hemorrhaging from lithotripter fields is increased for several hours after injection.
- As long as the recommended output limits of Section 2.4 are not exceeded, mechanical effects are far less likely to be important in obstetrical ultrasound because of the absence of gas bodies.

4. Rationale

4.1 Thermal Effects

One of the major mechanisms for adverse biological effects from ultrasound exposure of mammalian systems is the heating of tissue via absorption of the ultrasonic beam (NCRP 1992). Therefore, guidelines have been developed in terms of exposure parameters directly related to temperature rise and the biological effects of heating.

4.1.1 Exposure Parameters

Implementation of the recommendations in this document requires a basic knowledge of the meaning of the new primary exposure parameter, the **Thermal Index (TI)** (AIUM/NEMA 1998a, Lopez 1998). This index is an estimate of the maximum temperature rise which could occur in ultrasonically heated tissue during an ultrasound examination. To distinguish it from an actual temperature elevation, the **TI** is unitless, being normalized to a temperature elevation of 1 °C. However, in varying with changes in the user control settings, the **TI** is directly proportional to the potential for heating. The **Thermal Index** is computed from directly measurable properties of the ultrasonic field, as determined in water under standard conditions. The methods of measurement are described in the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* (AIUM/NEMA 1998b). The methods of computation are described in the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA 1998a). A computed index is used because it is not feasible to monitor the actual temperature elevation in a clinical examination. In addition, the complexity of the conditions also precludes calculation of the actual temperature elevation.

There are three user-selectable **TI** categories which can be displayed (AIUM/NEMA 1998a, Lopez 1998). The **Soft Tissue Thermal Index (TIS)** is meant to be displayed for examinations in which the ultrasound beam travels a path which is made up principally of homogeneous soft tissue or a soft tissue/fluid path, as in a first trimester fetal examination or an abdominal examination. The **Bone Thermal Index (TIB)** is applicable to examinations in which bone is exposed to

ultrasound, as could occur during Doppler blood flow examinations of a second or third trimester fetus. The **Cranial Bone Thermal Index (TIC)** pertains to examinations in which bone is at or very near the surface of the transducer, such as during transcranial, Doppler blood flow examinations.

A number of experimental and theoretical studies provide support for the three types of **Thermal Index**. Earlier studies have been thoroughly documented in two major reports on the subject (NCRP 1992, AIUM 1993). Since the publication of these documents, more recent clinical (Ramnarine, *et al.*, 1993, Siddiqi, *et al.*, (1995)) and experimental (Bosward, *et al.*, 1993, O'Neill, *et al.*, (1994), Duggan, *et al.*, 1995, Doody, *et al.*, 1999) research has provided further evidence to support the models used to determine the different types of **Thermal Index**. The *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA 1998a)also provides brief rationales for the different types of **Thermal Index**.

4.1.2 Biological Effects

The clinical effect of an exposure depends on the nature and degree of tissue injury. This can be assessed from biological effects studies. Several extensive reviews have been published regarding the adverse biological effects of **ultrasonic heating** based on animal studies, particularly in mammalian species (Lele 1985, NCRP 1992, WFUMB 1992, AIUM 1993, WFUMB 1998). With regard to adult tissues, the available literature suggests that tissue temperature elevations in the range of 8-10 °C, sustained for 1 to 2 minutes will cause tissue injury (Bly, *et al.*, 1992, Lele 1985). The reviews have also considered studies of teratogenic effects, usually on the developing brain, due to whole body heating of the embryo or fetus. The recommendations resulting from these reviews can be succinctly expressed as follows (WFUMB 1998):

(i) a diagnostic ultrasound exposure that produces a maximum *in situ* temperature rise of no more than 1.5 °C above normal physiological levels (37 °C) may be used clinically without reservation on thermal grounds,

(ii) a diagnostic ultrasound exposure that elevates embryonic and fetal *in situ* temperature above 41 °C (4 °C above normal temperature) for 5 minutes or more should be considered potentially hazardous,

(iii) the risk of adverse effects is increased with the duration of exposure.

In addition, it has been reported that water immersion body heating of rats yielded the development of encephalocoeles in the rat fetuses in as little as 1 minute at a temperature elevation of 5 °C above normal physiological temperature. (WFUMB 1998).

For temperature elevations greater than 1.5 °C above normal physiological levels (37 °C), this information can be approximately matched to a functional form recommended by the NCRP (NCRP 1992). This yields an equation for combinations of temperature elevation and time which should be considered potentially hazardous:

$$t = 4^{5-\Delta T}$$

where t is the time in minutes at the specified temperature and ΔT is the temperature elevation above normal (37 °C).

Barnett, *et al.*, (1997) have recently published an updated review of thermal effects, focussing on the potential for effects on the fetus. They note that there is little information on the teratogenic effects from localized heat damage by ultrasound.

4.1.3 Human Exposure and Clinical Significance

To determine whether an exposure is justified, the equipment operator must assess whether reliable diagnostic information can be achieved and the severity and likelihood of an adverse health effect. To address the potential effects due to heating, estimates of the maximum exposures from various devices have been made in terms of the AIUM/NEMA **Thermal Index** and a method recommended by the National Council for Radiation Protection and Measurement (NCRP 1992) for estimating maximum temperature elevations.

As indicated in Sections 3.2 and 4.1.2, the **dwell time** is also an important parameter when considering the potential for a biological effect due to heating. One study found that the **dwell time** in fetal Doppler carotid artery exams was in the range of 4 to 80 seconds with a mean of 31 seconds (Duggan and McCowan 1993).

An assessment of the clinical significance of **ultrasonic heating** from diagnostic ultrasound devices depends upon estimates of the potential acoustic exposure. For equipment available prior to the implementation of the Output Display Standard in 1993, Patton, *et al.*, (1994) found no real-time B-mode devices with **Thermal Indices** exceeding 1, consistent with the conclusions of the World Federation

for Ultrasound in Medicine and Biology (WFUMB 1998). The vast majority of M-mode devices yielded **Thermal Indices** less than 1, with the largest **TIB** being 1.4. The maximum **Thermal Indices** for general pulsed Doppler devices were 1.3 for soft tissue exposure (**TIS**) and 2.8 for exposure of bone (**TIB**). The majority of the Doppler console/transducer/mode/intended use combinations (samples) yielded **Thermal Indices** less than 1. For peripheral vascular devices, most of the samples yielded **TIB** values greater than 1. The maxima were 2.2 and 2.8, for soft tissue and bone respectively. For colour flow Doppler, six of the samples (19%) yielded **TIS** values greater than 1, with the maximum **Thermal index** being 2.3.

The results of one major survey of the directly measured properties of the ultrasound field, acoustic pressure and power, suggest that acoustic output may have risen since the implementation of the Output Display Standard. However, this is not clear from the information made available in the published study (Henderson, *et al.*, 1995). It is plausible that changes to the **U.S. FDA 510(k) guidance document** in 1993 have led to an increase in the number of devices with acoustic output approaching the limits recommended in Section 2.4. Although two surveys have been made of **Thermal Index** values since that time (Shaw, *et al.*, 1997, 1998), a comparison between devices sold before and after 1993 cannot be made from the published report.

If the path through the bladder for a 1st trimester fetal examination is more than 5 cm, computed estimates of the maximum temperature elevation according to the NCRP method (NCRP 1992) can exceed those given by the AIUM/NEMA **Thermal Indices** by as much as a factor of 2 – 3. The evidence on propagation paths during ultrasound examinations in the study by Ramnarine, *et al.*, (1993), suggests that the **TIS** might be exceeded by a factor of 2 – 3 for as many as 40% of 1st trimester transabdominal examinations where the path through the bladder is more than 5 cm.

However, other evidence supports the expectation that, only in more unusual circumstances, would the NCRP estimate indicate a significantly different need for exposure reduction than would be provided by the **TI**. For each diagnostic ultrasound device in the sample studied by Patton, *et al.*, (1994), the **TI** was compared to the NCRP estimates. It was found that about 95% of the **TIS** values were within a factor of 2 of the corresponding NCRP estimates. In addition, Bly, *et al.*, (1992) found that for 236 samples, the NCRP estimate of maximum temperature elevation did not exceed 1.6 °C for transabdominal, pulsed Doppler examination of a first trimester fetus. Other

calculations made for non-autoscanning transducers with well defined focusing geometries and **a derated spatial peak time average intensity, $I_{spta.3}$**, of 720 mW/cm^2, (Bly, *et al.*, 1992, AIUM 1993) also yielded computed estimates of maximum temperature elevation which were approximately 2 °C.

There is also evidence to support the expectation that for 2nd and 3rd trimester exposures, only in relatively unusual circumstances would the NCRP estimate indicate a significantly different need for exposure reduction than would be provided by the **TI**. First, in the study by Ramnarine, *et al.*, (1993), all of the propagation paths yielded ultrasound attenuation greater than or equal to 0.3 dB/cm-MHz, the value used as the basis for the tissue models in the Output Display Standard. Furthermore, the vast majority of samples in the study by Bly, *et al.*, (1992) yielded maximum temperature elevations of less than 4 °C for heating of second trimester fetal bone. In the study by Patton, *et al.*, (1994), the largest temperature elevation calculated according to the NCRP method was 5.9 °C. This occurred for a transducer with a 10.5 cm focal depth. This evidence suggests that only in highly unusual circumstances would there be a significantly different need for exposure reduction than would be provided by the **TI**.

Carstensen, *et al.*, (1992) addressed the potential for **ultrasonic heating** during an echocardiography examination. They considered the primary heating concern to be the patient's rib(s), particularly if the patient was not able to provide an indication of discomfort or pain. It was noted that this would be the case in some pediatric examinations. Carstensen and co-workers calculated that most diagnostic ultrasound devices would not be able to ultrasonically heat the ribs by more than 1.5 °C. However, they did indicate that 1 pulsed Doppler model appeared to have the capability of heating to about 3 – 6 °C.

The information provided above suggests that, in most clinical examinations, exposures are not sufficient to cause adverse health effects due to **ultrasonic heating**. However, the maximum temperature elevations resulting from ultrasound exposure during Doppler blood flow examinations can be well above the normal diurnal variation of 1 °C. Also, in rare circumstances, the maximum potential temperature elevations appear to be near to thresholds for tissue injury for plausible clinical **dwell times**.

Transducer self-heating has been known to occur with diagnostic ultrasound devices and it has the potential to be a substantial source of heating (Duck, *et al.*, 1989). Although the tissue heating should be

localized to the region near the contact surface, the additional heating could be a cause for concern during transcranial, transvaginal, transrectal or transesophogeal examinations (NCRP 1992, WFUMB 1998).

Surveys of diagnostic ultrasound devices sold in Canada were last made in 1990. They indicated that, normally, devices were sold with acoustic intensities less than the limits recommended in Section 2.4 of these guidelines. These limits effectively constrain the potential for **ultrasonic heating** by diagnostic ultrasound devices. Therefore, having these limits on the device and using the real-time display of **Thermal Indices,** it should be possible to ensure that there is very little risk to the patient from **ultrasonic heating**.

4.2 Mechanical Effects

In the absence of heating, biological effects at diagnostic exposure levels have been observed in mammalian tissues with stable gas bodies, such as lung (WFUMB 1998, AIUM 2000), and intestine. Such effects have also been observed in other tissues after injection of ultrasound gas contrast agents (microbubbles). Therefore, guidelines have been developed in terms of an exposure parameter directly related to mechanical (non-thermal) effects. At or below the recommended output limits of Section 2.4 (**MI** = 1.9), mechanical effects are far less likely to be important in obstetrical ultrasound because of the absence of gas bodies.

4.2.1 Exposure Parameter

Implementation of the recommendations in this document requires a basic knowledge of the meaning of the new primary exposure parameter for mechanical effects, the **Mechanical Index (MI)** (AIUM/NEMA 1998a, Lopez 1998). The development of the **Mechanical Index** has been described in detail elsewhere (AIUM/NEMA 1998a, AIUM 1993, Apfel and Holland 1991). It is approximately the largest **rarefaction pressure** (in MPa) in a soft-tissue attenuated ultrasound beam, divided by the square root of the centre frequency (in MHz) of the ultrasound pulse.

The **MI** is related to the potential for hemorrhaging of the pulmonary alveolar capillaries due to ultrasonic exposure of the lung during a diagnostic ultrasound examination. The threshold for lung hemorrhage depends on the ultrasonic pressure at the surface of the patient's lung,

divided by the square root of the centre frequency of the ultrasonic pulse (AIUM 1993). Although this quantity and the **MI** may not always be in direct proportion, in many cases, the **MI** provides a relative indication of the potential for lung hemorrhage due to ultrasound exposure. It can also provide an approximate relative indication of the potential for biological effects in the presence of contrast agents (AIUM 2000).

4.2.2 Biological Effects

Hemorrhaging of lung capillaries is the first and most thoroughly studied mechanical biological effect which has been observed in mammals at diagnostically relevant exposures. Beginning with the study by Child, *et al.*, (1990), this effect has also been observed in several laboratories and in several mammalian species when the lung was directly exposed by pulsed ultrasound (Dalecki, *et al.*, 1997, Baggs, *et al.*, 1996, Holland, *et al.*, 1996, Zachary and O'Brien 1995, Tarantal and Canfield 1994, Frizzell, *et al.*, 1994). The acoustic pressures, centre frequencies, pulse durations and pulse repetition rates were at diagnostically relevant values in the studies. The species included swine, rat, rabbit, monkey and mouse. The species with lungs most similar to humans were monkey and swine. Studies prior to 1993 have been summarized elsewhere (AIUM 1993). Some of the studies published after 1993 are summarized below in chronological order. More detailed reviews have also either been recently published or are in preparation (WFUMB 1998, AIUM 2000, NCRP in preparation).

Tarantal and Canfield (1994) reported findings of multiple, circular hemorrhagic foci of 1 – 10 mm diameter in the lungs of monkeys directly exposed by ultrasound. The lesions were usually near the pleural surface and appeared to originate from alveolar capillaries. A clinical scanner operating in "triple mode" (B-mode imaging + colour Doppler + pulsed Doppler)at maximum output was used to provide the exposure. The monkeys ranged in age from 3 months to 5 years (infant to young adult). The frequency was 4 MHz, with a pulse duration of 0.65 microseconds and a PRF of 1515 Hz. The **rarefaction pressure** was maximal at 1.2 cm depth where the **MI** was 1.8. The exposure duration was 5 minutes. The chest wall thickness in the monkeys was 0.3 to 1.2 cm and the transducer was held directly to the chest.

O'Brien and Zachary (1997) found evidence for lung hemorrhaging in adult rabbits and mice after exposure to pulsed wave ultrasound for 5 minutes with a commercial diagnostic ultrasound imaging system

operating at 3 and 6 MHz, with **MI** values between 0.8 and 2.2. All exposures were above threshold. However, in adult pigs(10 – 12 weeks old, weighing about 30 kg), no hemorrhaging was observed.

Dalecki and co-workers (Dalecki, *et al.*, 1997, Baggs, *et al.*, 1996) reported lung hemorrhaging in neonatal and 10 day old swine after exposure by a stationary 2.3 MHz ultrasound beam with a pulse length of 10 microseconds and a 100 Hz pulse repetition frequency. The exposure duration at a single location was between 10 s and 2 minutes. In water, at the surface of the animal, the maximum negative pressure at threshold was about 1.1 – 1.4 Mpa. The threshold pressure at the surface of the lung was reported as 0.7 – 1.0 MPa. This quantity divided by the square root of the centre frequency has a value between 0.5 and 0.7. Exposures at a pressure 1.5x the threshold value showed 1 – 1.5 mm focal hemorrhages. At a factor of 2 – 3 above threshold pressure, clearly defined hemorrhagic areas were observed with linear dimensions up to 6 mm. Damage was restricted to single lobules and all hemorrhages were subcapsular, with no rupture of the parietal pleura.

Dalecki, *et al.*, (1997) summarized the results of studies about the way in which the pressure threshold for lung hemorrhage depended on other parameters of the ultrasound exposure. These parameters included centre frequency, pulse duration and exposure duration (Holland, *et al.*, 1996, Child, *et al.*, 1990). The studies indicated that the pressure threshold increases as the square root of the centre frequency and that reducing the pulse duration by a factor of 10 increases the pressure threshold by a factor of 2. The threshold of lung hemorrhaging was found to be a weak function of exposure duration.

Meltzer, *et al.*,(1998) found no evidence of hemorrhaging after intraoperative transesophageal echocardiography in adults where the **MI** was 1.3.

There was also evidence of hemorrhaging in murine intestine (Dalecki, *et al.*, 1995) after 5 minutes of exposure to ultrasound exposure at diagnostically relevant frequencies, pulse durations (10 μs) and pulse repetition frequencies (100 Hz). The effect occurred in the absence of significant heating. At 2.4 and 3.6 MHz, the threshold pressure divided by the square root of the frequency was approximately 1.9.

A preliminary report has also been published by Skyba, *et al.*, (1998) of microbubble destruction of rat muscle capillaries *in vivo* using 2.3 MHz ultrasound at reported **MI** values ranging from 0.4 to 1. In another study, Miller and Gies (1998) injected mice with gas

contrast agents and demonstrated significant enhancements in the generation of petechiae in the mouse intestine due to pulsed ultrasound exposure at 1 MHz with a 10 microsecond pulse duration and exposure levels as low as 1 MPa.

Recently, a study has been published (Dalecki, *et al.*, 1999) that describes hemorrhaging in murine fetuses exposed to pulsed ultrasound with 10 microsecond pulses delivered with a pulse repetition frequency of 100 Hz. In this case, the hemorrhaging appeared near developing bone. Gas bodies did not appear to be a relevant factor. At 1.2 MHz, the negative pressure threshold for hemorrhage to the fetal head was about 2.5 MPa. No statistically significant hemorrhage was found at frequencies of 2.4 and 3.6 MHz at the highest negative pressure of 5 MPa.

4.2.3. Human Exposure and Clinical Significance

To determine whether an exposure is justified, the equipment operator must assess whether reliable diagnostic information can be achieved as well as the severity and likelihood of an adverse health effect.

Carstensen and co-workers (Carstensen, *et al.*, 1992, Baggs, *et al.*, 1996) discussed the likelihood of finding clinical ultrasound exposures above the thresholds for capillary lung hemorrhage found in the experimental studies noted in Section 4.2.2. Their conclusion was that the largest outputs available from equipment in 1992 were very near the thresholds of macroscopic hemorrhage of lung tissue, if exposure was directly over the lung in an echocardiographic exam. This was considered the most common way in which the lung would be exposed.

It is plausible that more recent devices have higher output levels and may exceed the thresholds for lung hemorrhaging for the type of exposure described above. The output levels for the devices considered by Carstensen and co-workers are expected to have been similar to those in the survey of Patton, *et al.*, (1994). In that study, it was found that 14 of 266 samples yielded **MI** values greater than 1, the largest being 1.3. However, current equipment has **MI** values as high as 1.9. This is the current limit for diagnostic ultrasound devices in the **U.S. FDA 510(k) guidance document**. Therefore, commercial devices with these values of **MI** appear to be able to generate suprathreshold levels.

The potential for lung hemorrhaging was found to be greater for less typical diagnostic procedures, where the focus of the sound beam

could strike the surface of lung tissue. Baggs, *et al.*, (1996) stated that this could occur if a standoff is used and the lung tissue is near the surface of the chest. They noted that the focus of the beam could also strike the surface of lung tissue at the far side of the heart, particularly in pediatric or transesophageal applications. In these circumstances, it is estimated that devices with **MI** values of 1.9 could lead to exposures above the thresholds for lung hemorrhaging; by about factors of 1.5 and 3 for 1 microsecond and 10 microsecond pulse lengths, respectively. The 1 microsecond pulse length is typical for Doppler and B-mode imaging exams, although pulse durations up to 10 microseconds are available in some pulsed Doppler modes. This indicates that, for such exposures, there is a risk of some pulmonary alveolar hemorrhaging of the capillaries for neonatal or infant examinations.

The evidence concerning the biological effects studies and the acoustic outputs of diagnostic ultrasound devices, suggests that a cautious but reasonable approach is to assume that, if **MI** exceeds 1, there is some risk of capillary hemorrhaging on the lung surface in diagnostic ultrasound examinations of neonates and infants in which the lung is exposed. However, the long term implications of the injury may not be serious (Baggs, *et al.*, 1996). For example, Tarantal and Canfield (1994) described the hemorrhage observed in their study as anatomically mild. In both monkey and swine studies, the pathology did not indicate any disruption of the alveolar architecture. Therefore, clinically, recovery of the lesions would be expected upon the resorption of blood and reconstitution of existing architecture. No symptoms suggestive of any respiratory distress would be expected because of the lung's ability to compensate and the focal nature of the hemorrhages. Although there are no published results on whether the outcome would differ in the presence of other disease, hemorrhaging could be more extensive in the presence of coagulation disorders.

It is unlikely that there would be any significant intestinal hemorrhaging, even at the highest **MI** values available. However, pathologic conditions inhibiting intestinal peristalsis or promoting submucosal gas collections may increase the likelihood of such an effect.

Although studies are preliminary and the clinical significance has not been demonstrated, it is important that equipment operators be aware of the increased potential for capillary damage during a diagnostic ultrasound examination when GCAs are used, particularly in applications where malignant tumours may be exposed.

A maximum attainable value of 1.9 for the **MI** greatly reduces the potential for clinically significant damage from mechanical effects during diagnostic ultrasound examinations. If thresholds for biological effects must be exceeded to obtain useful diagnostic information, an examination technique that uses the real-time display of the **Mechanical Index** should make it relatively easy to ensure that the risk to the patient from mechanical effects is clinically justified. Above biological effects thresholds, the **ALARA** principle can be implemented by lowering the **MI** and/or reducing the **dwell time** to help minimize the severity of any potential injury, if required.

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6. Glossary of Terms

ALARA (As Low As Reasonably Achievable): a principle which is used to reduce unnecessary, potentially hazardous exposure to individuals, by keeping doses As Low As Reasonably Achievable. As shown throughout this guideline, application of the ALARA principle to diagnostic ultrasound differs from its common usage in diagnostic X-ray imaging where it is assumed that there is no threshold exposure.

In the use of diagnostic ultrasound, there are three ranges of exposure, i.e., combinations of Thermal or Mechanical Indices and dwell time, that need to be considered. At exposures that are clearly below the thresholds for health effects, further reduction of exposure is not justified, whether it is via reductions in dwell time or acoustic output. There can also be exposures that are or may be above thresholds for health effects. In these cases, ALARA refers to using the lowest value of potentially hazardous exposure, i.e. combination of acoustic output and dwell time, needed to achieve the required diagnostic information.

Bone Thermal Index (TIB): the Thermal Index for an exposure model in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

Cranial Bone Thermal Index (TIC): the Thermal Index for an exposure condition in which the ultrasound beam passes through bone near the beam entrance into the body.

derated: a derated quantity is one which has been measured in water using standard methods and then multiplied by a derating factor. This accounts for attenuation of the ultrasound field by the tissue between the transducer and a particular location in the body along the beam axis. The derating factor is 0.3 dB/cm-MHz in these guidelines.

derated spatial peak time average intensity: the largest value in an ultrasound beam of any derated time averaged intensity.

dwell time: the amount of time that the transducer is actively transmitting ultrasound while staying in one place during part of an examination.

rarefactional pressure: the amplitude of a negative instantaneous ultrasonic pressure in an ultrasound beam

Soft Tissue Thermal Index (TIS): the Thermal Index for an exposure model in which the ultrasound beam heats primarily soft tissue.

spatial average, pulse average intensity at the face of the transducer: the spatial average,temporal average intensity at the face of the transducer divided by the duty factor, where the duty factor is the product of the pulse duration and the pulse repetition frequency.

spatial average, temporal average intensity at the face of the transducer: the time averaged intensity, averaged over the face of the transducer.

Thermal Index (TI): a quantity related to the potential for **ultrasonic heating**. It is proportional to a calculated or estimated temperature rise for model exposure conditions. The **Thermal Index** is given by the ratio of the ultrasonic power emitted by the transducer to the ultrasonic power required to raise tissue temperature by 1 °C for the model exposure conditions. In the calculation of all Thermal Indices, the average ultrasonic attenuation in the body is assumed to be 0.3 dB/cm-MHz along the beam axis (e.g., the ultrasonic intensity is reduced by 3 dB, a factor of 2, for a 5 MHz beam, 2 cm into the body along the beam axis.)

Mechanical Index (MI): a quantity related to the potential for mechanical effects during a diagnostic ultrasound examination. It is given by the ratio of the largest value in the ultrasound beam of any derated rarefactional pressure to the square root of the transducer frequency. The pressure is in Megapascals and the frequency is in MHz.

U.S. FDA 510(k) guidance document: a document prepared by and available from the Centre for Devices and Radiological Health, U.S. Food and Drug Administration, which provides information for manufacturers seeking U.S.marketing clearance of diagnostic ultrasound systems and transducers. It is intended to provide guidance in the preparation of a regulatory submission to the U.S. FDA and does not bind the FDA or the regulated industry in any manner.

ultrasonic heating: the heating of tissue (including bone) due to the absorption of ultrasound.

ultrasonic power: the total amount of ultrasound energy emitted by the transducer per unit time.